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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/150,947	09/10/1998	RAYMOND KAEMPFER	A31967-PCT-U	7084

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BAKER & BOTT
30 ROCKEFELLER PLAZA
NEW YORK, NY 101120228

EXAMINER

NAVARRO, ALBERT MARK

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 08/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/150,947

Applicant(s)

Kaempfer et al

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

4) Claim(s) 50-93 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 50-93 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) Other: _____

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DETAILED ACTION

Continued Prosecution Application

1. The request filed on August 20, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/150,947 is acceptable and a CPA has been established. An action on the CPA follows.

Additionally Applicants sequence amendment filed May 22, 2003 (Paper Number 29) has been entered.

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 84-92 have been renumbered as claims 85-93, respectively. Accordingly, claims 50-93 are pending in the instant application.

All grounds of rejection in the Office Action mailed March 20, 2001 are withdrawn.

The following new grounds of rejection are applied:

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Specification

3. Applicants are reminded that all claims of priority must be recited on the first line of the specification.

Abstract

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

Claim Rejections - 35 USC § 112

5. Claims 88-93 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Applicants newly filed claims recite SEQ ID NO: 13-18. However, none of these sequences have clear support from the specification as originally filed. Applicant argue that support can be found for the consensus amino acid sequences in the peptides of the present invention. (SEQ ID NO: 1-11). However, while SEQ ID NO: 1-11 provide support for claiming SEQ ID NO: 1-11, it does not follow that consensus sequences derived from these peptides are supported by the originally filed application. Accordingly Applicant is required to demonstrate clear support for the newly filed claims or cancel the new material. This requirement is also applicable to the newly filed sequence listing which recites SEQ ID NO: 13-18.

6. Claims 65-75 and 88-93 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 65-75 and 88-93 recite isolated peptides having the amino acid sequence of SEQ ID NO: 1-11, and 13-18.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ

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ID NO: 1-11 and 13-18 alone are insufficient to describe the genus. Thus, Applicant's have not described a function which is shared by the 10 amino acid fragments identified by SEQ ID NO: 1-11 and 13-18 which would adequately describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

As a suggestion, amendment of the claims to recite "consisting of SEQ ID NO: 1-11 and 13-18" would be sufficient to overcome this rejection.

7. Claim 76 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the recitation of "INF-(.)" Clearly the 1/2 of a parentheses is a typographical error, however, the use of abbreviations can result in numerous

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different compounds being represented by the same abbreviation. Amendment to fully recite the intended compound will be sufficient to overcome this rejection.

8. Claims 90 and 93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "X." It is noted that Applicants claim language sets forth that Xaa is an amino acid, however the limitations of "X" are simply not set forth.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 50-65, 68, 76-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Tice *et al.*

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The claims are directed to an isolated and purified peptide having an amino acid sequence homologous to an amino acid sequence of a domain of a pyrogenic exotoxin which domain forms a central turn in the exotoxin starting with β -strand 7 and connecting to the β -strand 7, via short β -strand 8, to α -helix 4, and ending with α -helix 4, based on the domain numbering of SEB, wherein said isolated peptide does not have toxin agonist activity and is capable of antagonizing toxin-mediated activation of T lymphocytes.

Tice *et al* (US Patent Number 5,407,609) disclose of 30 mg of formalinized staphylococcal enterotoxin B (SEB) dissolved in 100 μ L deionized water. (See column 8).

In view that the toxoid disclosed by Tice *et al* does not exhibit toxin agonist activity and is homologous to the features recited in the claim, the disclosure of Tice *et al* is deemed to anticipate the claimed invention.

10. Claims 89-90 and 92-93 are rejected under 35 U.S.C. 102(b) as being anticipated by Ratti *et al.*

The claims are drawn to a purified peptide having an amino acid sequence of SEQ ID NO: 14 or SEQ ID NO: 17, wherein said peptide does not have toxin agonist activity.

Ratti *et al* (EP 499 681) disclose of a protein encoded by ORF6D comprising nucleotides 5595-6335 obtained from Chlamydia trachomatis. Applicants attention is directed to page 14, line 10, which starts a peptide with the identical structural requirements set forth in the claims.

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11. Claim 88 is rejected under 35 U.S.C. 102(b) as being anticipated by Galinski *et al.*

The claims are drawn to a purified peptide having an amino acid sequence of SEQ ID NO: 13, wherein said peptide does not have toxin agonist activity.

Galinski *et al* (Virology Vol. 155, pp 46-60, 1986) disclose of a polymerase-associated nucleocapsid phosphoprotein obtained from parainfluenza virus, which meets the structural requirements set forth in the claim.

12. Claim 91 is rejected under 35 U.S.C. 102(b) as being anticipated by Spriggs *et al.*

The claims are drawn to a purified peptide having an amino acid sequence of SEQ ID NO: 16, wherein said peptide does not have toxin agonist activity.

Spriggs *et al* (J. Gen. Virol. Vol. 67, pp 2705-2719, 1986) disclose of a polymerase-associated nucleocapsid phosphoprotein obtained from parainfluenza virus, which meets the structural requirements set forth in the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached

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on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

August 6, 2003